Listing of Claims

Claims 1-5 and 7-16 are currently pending in the application.

Claim 1 (Currently amended) A sustained/prolonged release pharmaceutical formulation comprising:

(a) a water soluble medicament associated with; [and]

(b) a polymer mixture comprising a first component comprising about 80 weight percent of polyvinyl acetate combined with about 20 weight percent polyvinyl pyrrolidone of the total weight of said first component, combined with a second component comprising a cellulose ether polymer wherein said first component is present in an amount ranging from about 45 weight percent to about 90 weight percent of the total formulation.

Please cancel claim 2 without prejudice.

Claim 2 (Previously amended) A pharmaceutical unit dosage form which comprises:

(a) a water soluble medicament; and

(b) a polymer mixture comprising a first component present in an amount ranging from about 20 weight percent to about 90 weight percent of the total formulation combined with a second component comprising a cellulose ether polymer where said second component ranges from about 2 weight percent to about 60 weight percent of the total weight of the formulation.

Claim 3 (Twice amended) The [dosage form] formulation according to claim [2] 1 wherein said cellulose ether polymer is selected from the group consisting of methyl-, ethyl-, hydroxyethyl-, hydroxypropyl-, or hydroxypropyl methyl- substituted polymers of Methocel A series; hydroxypropyl methyl celluloses of METHOCEL E, F, J ,or K series at various viscosity grades; different viscosity grades of hydroxyl propyl celluloses of Klucel, or Methocel series; a low substituted grades of hydroxypropyl celluloses of the LH series; and ethyl celluloses of ETHOCEL P series, or a mixture of any of the foregoing ethers.

Claim 4 (Currently amended) The formulation according to claim [3] 1 wherein said water soluble medicament is selected from the group consisting of a pharmaceutically acceptable addition salt of hydroxyzine, a pharmaceutically acceptable addition salt of metoprolol, niacin, caffeine, theophylline, a pharmaceutically acceptable acid addition salt of diltiazem, a pharmaceutically acceptable acid addition salt of albuterol, a pharmaceutically acceptable acid addition salt of metformin, a pharmaceutically acceptable acid addition salt of metronidazole, a pharmaceutically acceptable acid addition salt of metoclopramide, a pharmaceutically acceptable acid addition salt of ranitidine, a pharmaceutically acceptable acid addition salt of captopril, a pharmaceutically acceptable acid addition salt of nefazodone, a pharmaceutically acceptable acid addition salt of zolpidem, a pharmaceutical acceptable acid addition salt of sertraline, a pharmaceutically acceptable acid addition salt of labetalol, and a pharmaceutically acceptable acid addition salt of atenolol.

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Please cancel claim 5 without prejudice.

Claim 5 (Previously amended) A pharmaceutical construct comprising:

(a) a water soluble medicament;

(b) a polymer mixture comprising (a') a first component comprising about 80 weight percent of polyvinyl acetate combined with about 20 weight percent polyvinyl pyrrolidone of the total weight of said first component; combined with (b') a second component comprising a cellulose ether polymer ranging in an amount of from about 20 weight percent to about 60 weight percent of the total weight of the formulation.

Claim 6 (Previously cancelled) The pharmaceutical construct as defined in claim 5, wherein said first component is present in an amount ranging from about 20 weight percent to about 90 weight percent of the total formulation and said second component ranges from about 2 weight percent to about 60 weight percent of the total formulation.

Please cancel claim 7 without prejudice.

Claim 7 (Previously amended) The pharmaceutical construct as defined in claim 5 wherein said cellulose ether is selected from the group consisting of methyl cellulose, hydroxyl propyl cellulose, hydroxy propyl methyl cellulose METHOCEL A series, METHOCEL E series, METHOCEL F series, METHOCEL K series, Metoloses LH series, ETHOCEL P series, or a mixture of any of the foregoing cellulose ethers.

Please cancel claim 8 without prejudice.

Claim 8 (Original) The pharmaceutical construct as defined in claim 7 wherein said water soluble medicament is selected from the group consisting of a pharmaceutically acceptable addition salt of hydroxyzine, a pharmaceutically acceptable addition salt of metoprolol, niacin, caffeine, theophylline, a pharmaceutically acceptable acid addition salt of diltiazem, a pharmaceutically acceptable acid addition salt of albuterol, a pharmaceutically acceptable acid addition salt of metformin, a pharmaceutically acceptable acid addition salt of metronidazole, a pharmaceutically acceptable acid addition salt of metoclopramide, a pharmaceutically acceptable acid addition salt of ranitidine, a pharmaceutically acceptable acid addition salt of captopril, a pharmaceutically acceptable acid addition salt of nefazodone, a pharmaceutically acceptable acid addition salt of zolpidem, a pharmaceutical acceptable acid addition salt of sertraline, a pharmaceutically acceptable acid addition salt of labetalol, and a pharmaceutically acceptable acid addition salt of atenolol.

Claim 9 (Currently amended) A process for the preparation of [a] the sustained/prolonged release pharmaceutical [unit dosage form] formulation of claim 1 comprising the steps of:

(a) fluidizing a water soluble medicament combined with a carrier, comprising a polymer mixture comprising a fist component, comprising about 80 weight percent of polyvinyl acetate combined with bout 20 weight percent of polyvinyl pyrrolidone of the total weight of said first component, combined with a second component comprising a cellulose ether polymer; to from a fluidized mixture;

(b) direct blending the mixture to form a granulated mixture; and

(c) tabletting said granulated mixture and/or blend to form a tablet.

Claim 10 (Original) The process according to claim 9 wherein said water soluble medicament is selected from the group consisting of a pharmaceutically acceptable addition salt of hydroxyzine, a pharmaceutically acceptable addition salt of metoprolol, niacin, caffeine, theophylline, a pharmaceutically acceptable acid addition salt of diltiazem, a pharmaceutically acceptable acid addition salt of albuterol, a pharmaceutically acceptable acid addition salt of metformin, a pharmaceutically acceptable acid addition salt of metronidazole, a pharmaceutically acceptable acid addition salt of metoclopramide, a pharmaceutically acceptable acid addition salt of ranitidine, a pharmaceutically acceptable acid addition salt of captopril, a pharmaceutically acceptable acid addition salt of nefazodone, a pharmaceutically acceptable acid addition salt of zolpidem, a pharmaceutical acceptable acid addition salt of sertraline, a pharmaceutically acceptable acid addition salt of labetalol, and a pharmaceutically acceptable acid addition salt of atenolol.

Claim 11 (Twice amended) The [dosage form] formulation as defined in claim [2] 1 which comprises a modulated release pharmaceutical construct having a matrix of water soluble medicament associated with a polymer mixture, where said mixture comprises said first component combined with [a] said second component and said medicament associated with said matrix.

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Please cancel claim 12 without prejudice.

Claim 12 (Original) A sustained release pharmaceutical composition comprising a construct comprising a water soluble medicament and a polymer mixture, comprising a first component comprising about 80 weight percent of polyvinyl acetate combined with about 20 weight percent of the total weight of said first component of polyvinyl pyrrolidone, combined with a second component comprising a cellulose ether polymer.

Claim 13 (Currently amended) A process for preparing [a] the sustained/prolonged release pharmaceutical formulation of claim 1 [unit dosage form], which comprises:

(a) blending a water soluble medicament with a polymer mixture comprising a first component, comprising about 80 weight percent of polyvinyl acetate combined with about 20 weight percent of polyvinyl pyrrolidone of the total weight of said first component, combined with a second component, comprising a cellulose ether polymer, to form a mixture; and

(b) tabletting said mixture.

Claim 14 (Currently amended) The process as defined in claim 13, wherein [the] said tabletting is conducted under direct compression.

Claim 15 (Original) The process as defined in claim 13 wherein said polymer and drug are blended by means of wet granulation followed by dry blending.

Claim 16 (Original) The process as defined in claim 13 wherein all material are wetted prior to said blending and dried and milled after said blending.

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